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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,261	09/25/2001	Ilse De Canck	IGJ-002	1026

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LAHIVE & COCKFIELD
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EXAMINER

MYERS, CARLA J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/04/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,261

Applicant(s)

CANCK ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-28-01.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 and 22-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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RESTRICTION

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the claims in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The method claims are improperly joined as the claimed methods require the detection of distinct target molecules. A reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5, 7-10, 13, 16, 17, 22 and 24, drawn to methods and primers for amplifying exon 2 of HLA-A, HLA-B and HLA-C, classified in class 435, subclass 24.33.

II. Claims 1-4, 7-9, 11, 14, 16, 22 and 25, drawn to methods and primers for amplifying exon 3 of HLA-A, HLA-B and HLA-C, classified in class 435, subclass 24.33.

III. Claims 1-4, 6-7, 9, 12, 15, 17, 22 and 23, drawn to methods and primers for amplifying exon 4 of HLA-A, HLA-B and HLA-C, classified in class 435, subclass 24.33.

3. The inventions are distinct, each from the other because of the following reasons:

Each of the claimed inventions is drawn to distinct polynucleotides and methods of amplifying said polynucleotides. Each of the polynucleotides of exon 2, exon 3 and exon 4 have different nucleotide sequences and different functional properties with respect to their use in

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diagnostic methods. Because of the differences in their structural and functional properties, the polynucleotides are distinct and unobvious over one another.

4. **Sequence Election**

In addition, each of the inventions detailed above each reads on patentably distinct inventions drawn to multiple SEQ ID Numbers. The sequences are patentably distinct from each other, and a further restriction is applied to each invention. Applicant must further elect a single set of primer pairs which amplify exon 2 of HLA-A, HLA-B and HLA-C.

Accordingly, Applicant should select a total of 6 primers which amplify the regions which correspond to the elected invention of either group I, II, or III as set forth above. In addition, Applicant must elect 3 single locus-specific target sequence from those target sequences set forth in claim 2, such that each of the elected loci correspond to and are amplified by the set of elected primers. It is noted that for each of the generic claims, the claims will be examined for their full scope. However, each claim that recites a specific primer or loci will be examined only to the extent that they read on the elected species. In response to this Office action, Applicants should clearly indicate which primer pairs are elected and the loci that correspond to each of these primer pairs.

It is noted that nucleotide sequences set forth in the claims are structurally distinct chemical compounds and are unobvious and distinct from one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an

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independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

5. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-III require different searches that are not co-extensive (e.g., a search for primers for amplifying exon 2 would not lead one to all primers for amplifying exon 3 or exon 4 of HLA-A, HLA-B or HLA-C), examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

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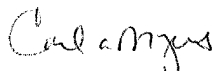
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

February 24, 2003


CARLA J. MYERS
PRIMARY EXAMINER